

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
Endocrinologic and Metabolic Drugs Advisory Committee Meeting
Hilton Washington DC North/Gaithersburg
July 15, 2010

AGENDA

The committee will discuss the safety and efficacy of new drug application (NDA) 22-580, proposed tradename QNEXA (phentermine/topiramate) Controlled Release Capsules, by VIVUS, Inc., as an adjunct to diet and exercise for weight management in patients with a body mass index equal to or greater than 30 kilograms (kg) per square meter, or a body mass index equal to or greater than 27 kg per square meter if accompanied by weight-related co-morbidities.

8:00 a.m.– 8:05 a.m.	Call to Order and Introductions	Kenneth Burman, M.D. <i>Committee Acting Chair</i> Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC)
8:05 a.m. – 8:15 a.m.	Conflict of Interest Statement	Paul Tran, R.Ph. Designated Federal Official EMDAC
8:15 a.m. – 8:30 a.m.	Introduction/Background	Eric Colman, M.D. Deputy Director Division of Metabolism and Endocrinology Products (DMEP), Office of Drug Evaluation (ODE) II Office of New Drugs (OND) Center for Drug Evaluation and Research (CDER) FDA
8:30 a.m. – 10:00 a.m.	Sponsor Presentation	Vivus, Inc.
	Unmet Medical Need	Louis Aronne, M.D. Clinical Professor of Medicine Weill-Cornell Medical College
	Clinical Pharmacology and Efficacy	Wesley Day, Ph.D. Vice-President, Clinical Development VIVUS, Inc.
	Neuropsychiatric Safety	Kishore Gadde, M.D. Director of Obesity Clinical Trials Program DUKE University Medical Center
	Safety REMS, Phase IV Outcomes Trial Benefit/Risk	Neil Gesundheit, M.D., M.P.H. Associate Dean for Advising Associate Professor of Medicine (Endocrinology) Stanford University School of Medicine

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	Pregnancy	Gideon Koren, M.D. Director, The Motherisk Program The Hospital for Sick Children Professor of Pediatrics, Pharmacology, Pharmacy and Medical Genetics University of Toronto
10:00 a.m. – 10:15 a.m.	Clarifying Questions from the Committee to Sponsor	
10:15 a.m. – 10:30 a.m.	Break	
10:30 a.m. – 11:30 a.m.	FDA Presentation	Mary Roberts, M.D. Clinical Reviewer DMEP, ODE II, OND CDER, FDA
11:30 a.m. – 12:00 p.m.	Clarifying Questions from the Committee to FDA	
12:00 p.m. – 1:00 p.m.	Lunch	
1:00 p.m. – 2:00 p.m.	Open Public Hearing Session	
2:00 p.m. – 2:30 p.m.	Questions from Committee to Sponsor and FDA	
2:30 p.m. – 2:45 p.m.	Break	
2:45 p.m. – 5:00 p.m.	Discussion/Questions to the Committee	
5:00 p.m.	Adjournment	